



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,397	10/25/2001	Bret A. Shirley	PP17201.003 (35784/240412)	3374

7590

09/04/2003

Chiron Corporation
Intellectual Property Department
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,397

Applicant(s)

SHIRLEY ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,9,10,12,19-22,27-30,41,42,45,46,49,50,53-56,59-67,75-81,85,87,95 and 97.

Continuation of Disposition of Claims: Claims rejected are 1-6,8,11,13-18,23-26,31-40,43,44,47,48,51,52,57,58,68-74,82-84,86,88-94,96 and 98-102.

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

Applicant's species election without traverse of aspartic acid in Paper No. 8 is acknowledged. Claims 1-102 are pending in this application. Claims 7, 9, 10, 12, 19-22, 27-30, 41, 42, 45, 46, 49, 50, 53-56, 59-67, 75-81, 85, 87, 95, and 97 are withdrawn from consideration as being drawn to non-elected species.

Specification

The disclosure is objected to because of the following informalities: There is a blank space on p. 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1646

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 11, 13-18, 23-26, 31-40, 43, 44, 47, 48, 51, 52, 57, 58, 68-74, 82-84, 86, 88-94, 96, and 98-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 5,004,605 (Hershenson et al., 1991) in view of the Merck Index, 1989, p. 859, column 2.

Hershenson et al. teaches stable compositions of interferon β , including recombinant IFN- β and the mutant IFN- β_{ser17} ; see columns 1 and 2. Both glycosylated and bacterially produced or non-glycosylated forms are taught (columns 1 and 2, column 7, lines 2-3). Hershenson et al. teaches compositions of these forms at pH 2-4, at a buffer concentration of 1-50 mM (column 4, lines 39-59). Interferon concentrations of .05- 10 mg/ml are taught (column 8, lines 61-65). Hershenson et al. teaches the use of polyethylene glycol as a stabilizing agent but also teaches that trehalose can be used as a stabilizer at concentrations of .025-10% (column 9, lines 21-31). Hershenson et al. fails to teach the use of aspartic acid as a buffer. The Merck Index teaches that aspartic acid has a pK_2 of 3.65. Thus, it would have been obvious to one of ordinary skill in the art to use aspartic acid to buffer the formulations taught by Hershenson et al. One of ordinary skill would have realized that aspartic acid would have optimal buffering

Art Unit: 1646

capacity at the pH range taught by Hershenson et al. and would thus have expected it to be useful in these formulations.

Claims 1-6, 8, 11, 13-18, 23-26, 31-40, 43, 44, 47, 48, 51, 52, 57, 58, 68-74, 82-84, 86, 88-94, 96, and 98-102 rejected under 35 U.S.C. 103(a) as being obvious over Hershenson et al. in view of U.S. patent 6,525,102 (Chen et al., 2003).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Hershenson et al. teaches as set forth above but fails to teach the use of aspartic acid. Chen et al. teaches stabilized compositions of interferon β , including IFN- β_{ser17} in column 12,

Art Unit: 1646

lines 29-32, and column 19, lines 30-40. That aspartic acid can be used in stabilizing these compositions is taught in column 5, lines 4, 20-56. Thus, it would be obvious to one of ordinary skill in the art to combine the teachings of Hershenson et al. and Chen et al. to use aspartic acid as a buffer in the compositions of Hershenson et al. One of ordinary skill would be motivated to do so because Hershenson et al. teaches stabilized compositions of interferon β and Chen et al. teaches a buffer useful for interferon β that also has stabilizing properties. Thus one of ordinary skill would have expected the buffer taught by Chen et al. to work at least as well as that exemplified by Hershenson et al.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.


Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

Art Unit: 1646

signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JANET ANDRES
PATENT EXAMINER

September 3, 2003